

### **Remarks**

This Amendment is submitted in response to the office action mailed September 2, 2009, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on December 2, 2009. Submitted herewith is a Request for Continued Examination Transmittal Form for the above-identified application. Accordingly, this Amendment is timely submitted.

Claims 26 through 51 are currently pending. Applicants respectfully request the entry of the amendments to Claims 26, 33 and 45 and cancellation of dependent claims 27, 34 and 46. Claim 26 has been amended to replace the phrase "through which" with the term "for" as submitted in the Amendment dated November 20, 2008. Claims 26, 33 and 45 have been amended to incorporate the subject matter of dependent claims 27, 34 and 46 respectively and to specify that the first channel is not contained within the channel of the second channel. Claims 26, 33 and 45 have been further amended to include minor grammatical corrections for clarity. In addition, claims 29, 36 and 48 have been amended to clarify that the atomizer further comprises the third channel. Support for the foregoing amendment is found throughout the original application including, for example, lines 6-12 of page 6, line 12 of page 7, lines 2-10 of page 6, line 4 of page 7 through line 19 of page 8 and Figures 2 through 4 of the original specification and the original claims as filed. Applicants respectfully submit that the amendments to this pending claim do not introduce any new matter.

### **Rejections under 35 U.S.C. § 102(b) and § 103(a)**

Claims 26, 27, 29-34, 36-41, 44-46 and 48-51 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Platz et al., U.S. Patent No. 6,051,256 (hereinafter "Platz"). The Examiner has reasserted that Platz shows a spray drying system for forming a pharmaceutical formulation comprising "an atomizer (57), the atomizer comprising a first, annular channel (100) through which a pharmaceutical liquid flows, the channel comprising a constriction (104) for spreading the pharmaceutical liquid into a thin film in the channel, the atomizer further comprising a second channel (102) through which an atomizing gas flows, the second channel being positioned so that the atomizing gas impinges the liquid thin film to produce droplets, a drying chamber (50) to dry the droplets to form particles; and a collector (76) to collect the particles." Further, Platz has been cited for teaching the constriction size, the third channel for gas flow, the specific inlet and outlet temperatures, the particles having a rugosity above 2, and/or a diameter of less than 20 micrometers. The Examiner has therefore concluded that Platz meets the limitations of the present invention as claimed.

Applicants respectfully submit that amended Claims 26, 29-33, 36-41, 44-45 and 48-51 are patentable under 35 U.S.C. §102(b) over Platz. Claims 27, 34 and 46 have been cancelled. Pursuant to 35 U.S.C. §102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), M.P.E.P. §2131. The identical invention must be shown in as complete detail as contained in ...the claims." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). "The elements must be arranged as required by the claim, but this is not an *ipsisssimis verbis* test, i.e., identity of terminology is not required." *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990), MPEP §2131.

The present invention is directed to a novel spray drying system for forming a pharmaceutical formulation that includes a new type of atomizer comprising (1) a first channel for a liquid flow, wherein said first channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) for spreading the liquid into a thin film in the channel; and (2) a second channel for an atomizing gas flow, wherein said first channel is not contained within the channel of said second channel and said second channel is positioned so that the atomizing gas impinges the liquid thin film to produce droplets. By utilizing these two independent channels for liquid and atomizing gas flow to form and impinge the thin film of liquid, the present invention has satisfied the existing need for an improved system capable of producing droplets having significantly more uniform and smaller diameter and spray dried particles having narrow size distribution.

Platz describes a different spray-drying method than the present invention of the present application. Platz is directed to a method for spray drying biological macromolecules using an two-fluid nozzle having two conduits -- an inner conduit (100) and an outer conduit (102 and 110) "disposed coaxially about" the inner conduit such that the outer conduit terminating orifice is "concentric about" the inner conduit terminating orifice. (See Platz, Column 13, line 64 to Column 14, line 9 and Figure 3.) The two-fluid nozzle described by Platz clearly requires the inner conduit (100) to be positioned within the outer conduit (102 and 110). In contrast to the present invention, Platz does not teach or disclose any atomizer having a first channel for a liquid flow "wherein said first channel is not contained within the channel of said second channel" as required by amended claims 26, 29-33, 36-41, 44-45 and 48-51.

Contrary to the Examiner assertion, Platz does not teach or disclose any "first annular channel (100)" comprising "a constriction (104) for spreading the pharmaceutical liquid into a thin film in the channel". (Office Action, page 3.) Platz describes a two-fluid nozzle including an inner conduit having a terminating orifice solely capable of producing a liquid stream as illustrated in Figure 3. Nowhere does Platz disclose that the inner conduit of the two-fluid nozzle forms a thin

film of liquid or contains any structure capable of forming a thin film of liquid as required by amended claims 26, 29-33, 36-41, 44-45 and 48-51.

Platz further does not teach or suggest any second channel "positioned so that the atomizing gas impinges the liquid thin film" to produce droplets as required by amended claims 26, 29-33, 36-41, 44-45 and 48-51.

Applicants respectfully submit that Claims 29-32, 36-41, 44 and 48-51 are in condition for allowance as they depend from an allowable independent claim. Further, Platz does not teach or suggest a third channel comprised within an atomizer to provide atomizing gas as required by amended Claims 29, 36 and 48. Figure 2 of Platz only illustrates that the supply of air for drying the formed droplets after any atomization has occurred.

Platz is directed to a different spray drying method than the present invention. Since each and every limitation of the pending claim is not inherently or expressly described, Platz does not anticipate amended claims 26, 29-33, 36-41, 44-46 and 48-51 under 35 U.S.C. §102(b).

Thus, in view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of Claims 26, 27, 29-34, 36-41, 44-46 and 48-51 are rejected under 35 U.S.C. §102(b).

Claims 28, 35, 42, 43 and 47 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Platz. The Examiner has asserted that dependent claims are obvious since the limitation "for spreading the pharmaceutical liquid into a thin film" is a recitation of the intended use of the first channel of the claimed invention. The Examiner further asserts that the dependent claims are obvious since "there is no further structure being claimed that differentiates the second channel of the claimed invention [from] the second channel of Platz."

The Applicants respectfully submit that Claims 28, 35, 42, 43 and 47, as amended, are patentable since a *prima facie* case of obviousness has not been established. A *prima facie* case of obviousness must establish that the prior art reference or combination of references teach or suggest all the claimed limitations. M.P.E.P. § 2143. Each dependent claim incorporates each and every limitation of each claim from which it depends. Applicants hereby incorporate by reference its above arguments setting forth the differences between Platz and the present invention of amended independent claims 26, 33 and 45.

As explained above for independent claims 26, 33 and 45, the present invention is directed to a spray drying system for forming a pharmaceutical formulation that includes a new type of atomizer comprising (1) a first channel for a liquid flow, wherein said first channel comprises a constriction having a diameter less than 0.51 mm (0.020 in) (for dependent claims 42 and 43) or less than 0.1 mm (0.005 in) (for dependent claims 28, 35 and 47) for spreading the liquid into a thin film in the

channel; and (2) a second channel for an atomizing gas flow, wherein said first channel is not contained within the channel of said second channel and said second channel is positioned so that the atomizing gas impinges the liquid thin film to produce droplets. By utilizing these two independent channels for liquid and atomizing gas flow to form and impinge the thin film of liquid, the present invention has satisfied the existing need for an improved system capable of producing droplets having significantly more uniform and smaller diameter and spray dried particles having narrow size distribution.

Platz describes a different spray-drying method than the present invention of the present application. Platz is directed to a method for spray drying biological macromolecules using an two-fluid nozzle having two conduits -- an inner conduit (100) and an outer conduit (102 and 110) "disposed coaxially about" the inner conduit such that the outer conduit terminating orifice is "concentric about" the inner conduit terminating orifice. (See Platz, Column 13, line 64 to Column 14, line 9 and Figure 3.) The two-fluid nozzle described by Platz clearly requires the inner conduit (100) to be positioned within the outer conduit (102 and 110). In contrast to the present invention, Platz does not teach or disclose any atomizer having a first channel for a liquid flow "wherein said first channel is not contained within the channel of said second channel" as required by pending claims 28, 35, 42, 43 and 47. This structural limitation of the pending claims is not taught or suggested by Platz.

The Examiner has incorrectly asserted that the limitation of claims 28, 35 and 47 requiring the first channel constriction to have a diameter less than 0.1 mm (0.005 in) would be an obvious obvious modification to one of ordinary skill in the art at the time the invention was made in view of Platz. On page 5 of the Office Action, the Examiner concludes that the claimed invention of claims 28, 35 and 47 is not patentably distinct from Platz since it "would not perform differently than" Platz. Applicants respectfully submit that this limitation is not merely a modification of relative dimensions. One of ordinary skill would not modify Platz as suggested by the Examiner since Platz identifies the orifice diameter of "0.015 in to 0.075 in, preferably from 0.025 to 0.05 in" to achieve the required liquid flow rate for atomization and further modification to use a smaller diameter orifice would be expected to impact the atomization process by slowing the liquid flow rate.

By incorporating an atomizer comprising (1) a first channel (for a liquid flow) comprising the specified constriction for spreading the liquid into a thin film in the channel; and (2) a second channel (for an atomizing gas flow) positioned so that the atomizing gas impinges the liquid thin film to produce droplets, wherein said first channel is not contained within the channel of said second channel, the present invention of claims 28, 35, 42, 43 and 47 produce significantly smaller and more uniform liquid droplet sizes than Platz. The technical data on page 8, lines 21-30 and Figure

5 of the original specification provides a direct comparison between the present invention over Platz:

The atomizer 40 according to the invention provides significantly improved atomization efficiency and allows for the ability to create smaller and more uniform liquid droplet sizes. For example, droplets less than 35 microns, and preferably less than 10 microns may be generated. The advantage of smaller droplet sizes is that a smaller final particle size for a given solid concentration may be obtained. Alternatively, a solid concentration may be increased while maintaining a particular particle size. This would allow for increased system throughput. The increased size distribution is shown in FIG. 5. FIG. 5 shows a graph of droplet diameter as a function of radial distance from the centerline of the atomizer for both the atomizer 40 of FIG. 4 and a prior art atomizer of U.S. Pat. No. 6,051,256. As can be seen, the droplet diameter is significantly more uniform and smaller for the atomizer 40 of the present invention.

(Page 8, lines 21-30 of the original specification.) Platz and the present invention of Claims 28, 35, 42, 43 and 47, as amended, are directed to structurally and functionally different spray drying systems.

Thus, in view of the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of Claims 28, 35, 42, 43 and 47 under 35 U.S.C. § 103(a).

In view of the foregoing arguments, Applicants respectfully request that the claims of the present application be reconsidered for allowance. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone her at the telephone number provided below.

Respectfully submitted,

  
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